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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,394	02/24/2004	Steve A. Yon	137001	6524
7590	09/07/2005		EXAMINER	
Mark D. Wieczorek, Ph.D., Esq. Innercool Therapies, Inc. 3931 Sorrento Valley Boulevard San Diego, CA 92121			GIBSON, ROY DEAN	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/785,394	YON, STEVE A.
	Examiner Roy D. Gibson	Art Unit 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 31 and 32 is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/10/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

Claims 6-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 10 recite the limitation "the inlet lumen" in line 1. There is a lack of proper antecedent basis for this limitation in the claim. The examiner suggests changing "inlet " to 'supply" to correct this.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-13, 16-21 and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Dae (6,231,594).

Dae discloses a catheter system and its method of use to change the temperature of blood by heat transfer to and from a circulating working fluid, comprising:
a supply lumen (130 into 114) made of a flexible and inflatable material forming a balloon to introduce the working fluid;
a return lumen comprising three helical output lumens (108, 110 and 112)

also made of flexible and inflatable material forming a balloon, wherein the cross-sectional area of the return lumens is greater than that of the supply lumen (Figure 22); wherein the working fluid is saline; wherein the supply or inlet lumen is about 25 centimeters in length (within the range of 5-30 cm); and wherein the diameter of the helical shape of the output lumens is about 9 F or 3 mm (less than 8 mm) when inflated (Figures 13-22 and col. 21, lines 5-16, col. 13, lines 30-46 and col. 24, line 38-col. 26, line 43).

Further to claims 12 and 27 and claims 13 and 28, Dae discloses a pump (Figure 24, # 244) which inherently applies pressure to the circulating saline working fluid at below 5 atmospheres and at a typical temperature about 0 degrees C (within the range of -3 to 36 degrees C and col. 18, lines 18-54).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dae in view of Daikuzono (5,609,591). Dae discloses the balloon material forming the inlet and return lumens to be made from a thin plastic material (col. 24, 29-37). But, Daikuzono teaches an alternative equivalent balloon catheter material made of latex rubber as an example of well known material in the art for such balloon catheters.

Claims 14, 15 and 29 -30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dae in view of Pecor (6,287,326). Dae fails to disclose the output lumen includes a surface coating or treatment to inhibit clot formation including heparin. But, Pecor discloses a catheter with a coiled multi-lumen heat transfer extension wherein a coating of heparin is applied to the outer portions of the heat transfer tube of lumen to discourage or inhibit clotting of blood surrounding the catheter (col. 7, lines 54-58). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art of medical catheters to modify the device of Dae, as taught by Pecor, to provide an anti-clotting agent to the exterior surface of the return lumen(s), thus inhibiting clotting of blood surrounding the catheter.

Allowable Subject Matter

Claims 31-32 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gobin et al. (6,409,747) disclose an indwelling heat exchange catheter which anticipates claims 1, 9, 12-16, 24, 27, and 28; and Tzeng et al. (6,589,271) disclose an indwelling heat exchange catheter which anticipates claims 1, 9, 12, 13, 16, 24, 27 and 28.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson
Primary Examiner
Art Unit 3739

September 2, 2005